K090578

MAQUET

Special 510(k): Device Modification: QUART Arterial Filter with Softline Coating

510(k) SUMMARY
[as required by 21 CFR 807.92]

DEC 18 2009

SUBMITTER:	MAQUET Cardiopulmonary AG Hechinger Strasse 38 72145 Hirrlingen, Germany
CONTACT PERSON:	Dr. Ingrid Richter Phone: (011) 49 7478 921- 337 Fax: 011 49 7478 921- 400
DATE PREPARED:	February 24, 2009
DEVICE TRADE NAME:	QUART Arterial Filter with SOFTLINE COATING
COMMON/USUAL NAME	Arterial Filter, coated
CLASSIFICATION NAME	Filter, Blood, Cardiopulmonary Bypass, Arterial Line
PREDICATE DEVICES OR LEGALLY MARKETED DEVICES	QUART Arterial Filter with Safeline Coating (K061546) QUADROX-i Adult microporous membrane Oxygenator with and without integrated Arterial Filter with SOFTLINE COATING (K082117)

DEVICE DESCRIPTION
The QUART Arterial Filter serves as a filter during extracorporeal circulation procedures to safely remove gaseous embolisms and aggregates from blood components in the arterial blood line.
Utilization of the QUART Arterial Filter therefore reduces the patient risk of injury from a micro-embolism resulting from gases or solids.

INDICATONS FOR USE
The QUART Arterial Filter with SOFTLINE COATING is designed for use in an extracorporeal circulation system during surgical procedures involving a cardiopulmonary bypass. Within the cited flow rates, the QUART arterial filter removes particulate and gaseous micro-embolisms from the extracorporeal circulation system. The eliminated gas can be removed via the purge line. The max. flow rate of the QUART Arterial Filter is 7l/min.

The decision regarding the method in which the arterial filter is to be employed rests solely with the treating physician.
The unit may not be continuously employed for more than 6 hours. We do not recommend longer contact with the blood.

STATEMENT OF TECHNICAL CHARACTERISTICS COMPARISON
The QUART Arterial Filter with SOFTLINE COATING is identical to the QUART Arterial Filter, with Safeline Coating with the only exception that the QUART Arterial Filter with SOFTLINE COATING has been coated with SOFTLINE. The SOFTLINE COATING is the same as with the QUADROX-i Adult microporous membrane Oxygenator with and without integrated Arterial Filter with SOFTLINE COATING. Besides this difference the both QUART Arterial Filters are the same in design, intended use, method of operation, components, packaging, and fundamental scientific technology.

DETERMINATION OF SUBSTANTIAL EQUIVALENCE
Evaluation and testing on safety and effectiveness was executed to demonstrate that the QUART Arterial Filter with SOFTLINE COATING described in this submission is substantially equivalent to the QUART Arterial Filter with Safeline Coating as an arterial filter and to the QUADROX-i Adult microporous membrane Oxygenator with and without integrated Arterial Filter with SOFTLINE COATING regarding the SOFTLINE COATING.

The following areas have been tested and / or evaluated:

- Integrity
- Performance
- Biocompatibility
- Sterility

CONCLUSION
The data given demonstrate that the QUART Arterial Filter with SOFTLINE COATING is substantially equivalent to the named predicate devices which hold currently market clearance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Maquet Cardiopulmonary AG
c/o Dr. Ingrid Richter
Regulatory Affairs Manager
Hechinger Strasse 38
72145 Hirringen
Germany

DEC 1 8 2009

Re: K090518
Maquet QUART Arterial Filter with Softline Coating
Regulation Number: 21 CFR 870.4260
Regulation Name: Filter, Blood, Cardiopulmonary Bypass, Arterial Line
Regulatory Class: Class II (two)
Product Code: DTM
Dated: November 23, 2009
Received: November 25, 2009

Dear Dr. Richter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090518

Device Name: QUART Arterial Filter with SOFTLINE COATING

Indications for Use:

The QUART Arterial Filter with SOFTLINE COATING is designed for use in an extracorporeal circulation system during surgical procedures involving a cardiopulmonary bypass. Within the cited flowrates, the arterial filter removes particulate and gaseous micro-embolisms from the extracorporeal circulation system. The eliminated gas can be removed via the purge line. The max. flow rate of the QUART Arterial Filter is 7l/min.
The decision regarding the method in which the arterial filter is to be employed rests solely with the treating physician.
The unit may not be continuously employed for more than 6 hours. We do not recommend longer contact with the blood.

Prescription Use ___X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K090518